IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

MDL No. 2327
In Re Ethicon Inc., Pelvic Repair System Products Liability Litigation

---

FIRST AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through counsel, bring this First Amended Master Long Form Complaint ("First Amended Master Complaint") as an administrative device to set forth potential claims individual Plaintiffs may assert against Defendants in this litigation. By operation of the Order of this Court, all allegations pled herein are deemed pled in any previously filed Complaint and any Short-Form Complaint hereafter filed. Accordingly, Plaintiffs allege as follows:

I. PARTIES

A. Plaintiffs

1. Plaintiffs include women who had one or more of Defendants' Pelvic Mesh Products (defined below) inserted in their bodies to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence.

2. Plaintiffs also include the spouses and intimate partners of the aforesaid women, as well as others with standing to file claims arising from Defendants' Products.

B. Defendants

3. Defendant, Johnson & Johnson ("J&J") is a corporation, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to

coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its' pelvic floor repair products. Within J&J there are three sectors, medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the pelvic floor repair products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD.

4. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant Johnson & Johnson located in Somerville, New Jersey.

5. Defendant, Ethicon, LLC, is a wholly owned subsidiary of Johnson & Johnson Medical, Inc., located in San Lorenzo, Puerto Rico. Ethicon LLC was charged by J&J with the manufacture of Ethicon Inc.'s pelvic floor repair products.

6. Defendants, JOHN DOES 1-20 (fictitious names), are entities and/or persons who are liable to Plaintiffs, but who have not yet been identified despite reasonable due diligence on the part of Plaintiffs.

7. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Prolene Mesh/Prolene Soft Mesh, Gynemesh, Gynemesh PS, TVT, TVT-Obturator (TVT-O), TVT-SECUR (TVT-S), TVT Exact, TVT Abbrevo, Prolift, Prolift +M, Prosima and other pelvic mesh products unknown at the present (hereinafter collectively referred to as "Pelvic Mesh

Products" or the "Products"). Defendants manufacture, market, advertise, promote and sell Pelvic Mesh Products worldwide. As a result of the coordinated activities of all Defendants named above, Plaintiff was implanted with a defective pelvic floor repair product.

8. Defendants had a legal duty to insure the safety and effectiveness of their pelvic mesh products by conducting adequate and well controlled studies on their products prior to marketing. Defendants deliberately chose to manipulate the only studies that were conducted on their products and by so doing provided doctors and patients with false and misleading information about the safety and effectiveness of their pelvic mesh products. Furthermore, Defendants made a conscious decision to forego performing studies and creating registries that would have provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of their pelvic mesh products.

II. JURISDICTION AND VENUE

9. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that in each of the constituent actions there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds $75,000.

10. Defendants have significant contacts with the federal judicial district identified in the Short Form Complaint such that they are subject to the personal jurisdiction of the court in said district.

11. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Pursuant to 28 U.S.C. § 1391(a), venue is proper in said district.

III. DEFENDANTS' PELVIC MESH PRODUCTS

12. In or about October, 2002, Defendants began to manufacture, market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

13. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants' Prolene mesh hernia product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

14. On or about January l, 2005, without seeking FDA clearance, the Defendants began to market and sell a product known as the Prolift System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The ProliftSystem was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift and/or Prolift System include by reference all variations.

15. On or about May, 2008, the Defendants began to market and sell a product known as Prolift+M System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M System was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift+M and/or Prolift +M System include by reference all variations.

16. On or about March 2010, Defendants began to market and sell a product known as Prosima System, for the treatment of medical conditions in the female pelvis, primarily

pelvic organ prolapse and stress urinary incontinence. The Prosima was and is offered as an anterior, posterior, or total repair system, and all references to Prosima include by reference all variations.

17. The Defendants market and sell a product known as TVT, for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple and significant variations including, but not limited to, the TVT, TVT-Obturator (TVT-O), TVT-SECUR (TVT-S), TVT Exact and TVT Abbrevo. All references to TVT include by reference all variations.

18. As stated above, the products known as Prolene Mesh, Gynemesh, Prolift, Prosima, Prolift+M, and TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' "Pelvic Mesh Products" or the "Products".

19. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, sold and distributed by the Defendants, at all times relevant herein.

IV. FACTUAL BACKGROUND

20. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Manufacturers, including Defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP an SUI. Today, defendants sell pelvic mesh "kits" which can include not only the surgical mesh, but also

tissue fixation anchors and insertion tools. The Products manufactured by Defendants are considered Class II medical devices.

21. Defendants' Pelvic Mesh Products are targeted for women who suffer from pelvic organ prolapse and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. These products are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

22. Moreover, these Pelvic Mesh Products contain polypropylene mesh. Despite claims that this material is inert, the scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' Pelvic Mesh Products. This immune response promotes degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of severe adverse reactions to the mesh.

23. At various times, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. This clearance process did not require Defendants to prove the safety or efficacy of the Pelvic Mesh Products and, thus, a formal review of the safety and efficacy of the Pelvic Mesh Products was never conducted with regard to the Products. In the case of the Prolift product, Defendants marketed and sold the product for human implantation for over two years without the necessary clearance under Section 510(k)

24. Defendants' Pelvic Mesh Products have been and continue to be marketed to the medical community and directly to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing Pelvic Mesh Products.

25. The Defendants have marketed and sold the Pelvic Mesh Products to the medical community at large and directly to patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the Pelvic Mesh Products. Defendants' further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out these products for implantation into their bodies.

26. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of the Pelvic Mesh Products and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as a safe medical device when, in fact, Defendants knew that the Pelvic Mesh Products were not safe for their intended purposes and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, catastrophic and permanent injuries.

27. For example, Defendants described in its Patient Brochures, Instructions for Use, and other marketing materials, that the known complications for its Pelvic Mesh Products were consistent with any surgical procedure of an implantable medical device and described such occurrences as "rare" and "small" when in fact Defendants knew or should have known that the complications were not "rare nor small" but common, permanent, and debilitating.

28. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Products have high malfunction, failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiffs, making them defective under the law. The Products' defects include, but are not limited to, the following:

a. the use of polypropylene material in the mesh itself and the immune reaction that results, causing adverse reactions and injuries;

b. in the case of the Prolift + M, the use of polypropylene in combination with monocryl, a partially dissolvable mesh that increases the immune reaction and inflammatory response;

c. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

d. the procedure itself, which is a part of the Pelvic Mesh Products, requires to the physician to insert the device "blindly," resulting in nerve damage and damage to other internal organs;

e. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury;

f. the lack of porosity in the mesh resulting in the formation of a scar plate that prohibits tissue in-growth, resulting in mesh contraction, nerve damage, pain, and erosion of the mesh into other organs, and failure of the device;

g. the use and design of anchors in the Pelvic Mesh Products which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

h. degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury;

i. particle loss and or "shedding" of the mesh both during implantation and following implantation that results in additional undesirable complications including an increased inflammatory response and a migration of those particles resulting in injury.

j. the welding and heating of the mesh itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike;

k. the design of trocars, as devices to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries;

l. the propensity of the mesh for "creep", or to gradually elongate and deform when subject to prolonged tension inside the body;

m. the propensity of the mesh to contract, retract, and/or shrink inside the body;

n. the inelasticity of the mesh, causing them to be improperly matted to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

o. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturer's instructions.

29. Upon information and belief, the Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and

safety of the Pelvic Mesh Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

30. Defendants have further deliberately chosen to forego the conduct of studies and registries to avoid reporting obligations that would be mandated under the federal regulations upon receipt of adverse event information.

31. Despite the chronic underreporting of adverse events associated with the Defendants' Pelvic Mesh Products, the underreporting of events associated with similarly designed competitor products, and Defendants' deliberately avoiding the conduct of studies and registries to avoid the reporting of adverse events, eventually enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

32. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to Pelvic Mesh Products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendants are one of the manufacturers of the Pelvic Mesh Products that are the subject of the notification.

33. On July 13, 2011, the FDA issued a Safety Communication:" UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of "continuing serious concern." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were "not rare."

These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization.

34. The FDA concluded in its Safety Communication that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh or repair of SUI with mesh kits are more effective than traditional non mesh repair of pelvic organ prolapse. Further, the FDA conducted a systematic review of the published scientific literature from 1996-2011 and concluded that based thereon, that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." The FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible."

35. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13 2011, was known or knowable to Defendants and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use, or labeling.

36. In fact, at the time Defendants began marketing each of its Pelvic Mesh Products, Defendants were aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

37. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (“ACOG”) and the American Urogynecologic Society

("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

38. Defendants knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

39. Defendants also knew or should have known that: (1) some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices (including a medical device known as Protogen device); (2) that there were and are differences between the Defendants' Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; (3) that significant differences exist and existed between the Pelvic Mesh Products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and (4) that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications.

40. The Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, and the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into Plaintiff.

41. Defendants' Pelvic Mesh Products are also defective due to Defendants' failure to adequately warn or instruct the female Plaintiffs named in the Short Form Complaint and/or her health care providers of risks and complications including, but not limited to, the following:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, fragmentation and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the Products' lack of porosity in preventing proper mating with the pelvic floor and vaginal region.

e. the rate and manner of mesh erosion or extrusion;

f. the risk of chronic inflammation resulting from the Products;

g. the risk of chronic infections resulting from the Products;

h. the risk of permanent vaginal or pelvic scarring as a result of the Products;

i. the risk of permanent vaginal shorting as a result of the Products;

j. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

k. the need for corrective or revision surgery to adjust or remove the Products;

l. the severity of complications that could arise as a result of implantation of the Products;

m. the hazards associated with the Products;

n. the Products' defects described herein;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

p. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

q. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

r. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

s. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

t. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain; and

u. the fact that neither pelvic organ prolapse, nor stress urinary incontinence, are life threatening conditions, and that other options, including non-surgical options, were available and superior alternatives to the use of the Products.

42. Defendants also failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of their Pelvic Mesh Products.

43. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products. Therefore, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

44. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

45. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

46. Furthermore, the Defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of the Pelvic Mesh Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

47. The Pelvic Mesh Products implanted into the Plaintiffs were in the same or substantially similar condition as they were when they left the possession of Defendants, and in the condition directed by and expected by the Defendants.

48. Plaintiffs and Plaintiffs' physicians foreseeably used and implanted the Pelvic Mesh Products, and did not misuse or alter the Pelvic Mesh Product in an unforeseeable manner.

49. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), inability to engage in sexual relations, urinary problems, inability to void, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, shortening of the vagina, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

50. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' Pelvic Mesh Products, have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

51. Defendants misrepresented to the medical and healthcare community, Plaintiffs, the FDA, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

52. In the case of the Prolift device, Defendants misrepresented to the Plaintiffs, to the Plaintiffs' physicians, and to the medical community at large, that such product had been properly cleared for marketing by the FDA when in fact no such clearance had been sought or obtained.

53. These representations were made by Defendants with the intent of inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced an indifference to the health, safety, and welfare of Plaintiff.

54. Defendants failed to undertake their duties to properly know the qualities of their Pelvic Mesh Products and in representations to Plaintiffs and/or to Plaintiffs' healthcare providers, and concealed and intentionally omitted the following material information:

a. That the Pelvic Mesh Products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the Pelvic Mesh Products were not as effective as other products and procedures available to treat incontinence and/or prolapsed;

c. That the risk of adverse events with the Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

d. That the risk of adverse events with the Pelvic Mesh Products were not adequately tested and were known by Defendants;

e. That the limited clinical testing revealed the Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

f. That Defendants failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

g. That Defendants were aware of dangers in the Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

h. That the Pelvic Mesh Products were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

i. That patients needed to be monitored more regularly than usual while using the Pelvic Mesh Products and that in the event the Pelvic Mesh Products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly; Thus:

j. That the Pelvic Mesh Products were manufactured negligently;

k. That the Pelvic Mesh Products were manufactured defectively; and

l. That the Pelvic Mesh Products were designed negligently, and designed defectively.

55. Defendants were under a duty to disclose to Plaintiffs and Plaintiffs' physicians, the defective nature of the Pelvic Mesh Products, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

56. Defendants had sole access to material facts concerning the defective nature of the Pelvic Mesh Products and their propensity to cause serious and dangerous side

effects and hence, cause dangerous injuries and damage to persons who used the Pelvic Mesh Products.

57. Defendants' concealment and omissions of material fact concerning the safety of the Pelvic Mesh Products were made to cause the Plaintiffs, the Plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the Pelvic Mesh Products; and/or to mislead Plaintiffs and Plaintiffs' physicians into reliance and cause Plaintiffs to have the Pelvic Mesh Products implanted into their bodies.

58. At the time these representations were made by Defendants, and at the time Plaintiffs used the Pelvic Mesh Products, Plaintiffs were unaware of the falsehood of these representations, and reasonably believed them to be true.

59. Defendants knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

60. In reliance upon these false representations, Plaintiffs were induced to, and did use the Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiffs and Plaintiffs' physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Pelvic Mesh Products, as described in detail herein.

61. As a result of Defendants' research and testing or lack thereof, Defendants distributed false information, including but not limited to assuring Plaintiffs, the public, and Plaintiffs' healthcare providers and physicians, that the Pelvic Mesh Products were safe for use

as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. Further, Defendants misrepresented to the Plaintiffs and to the Plaintiffs' physicians that the Pelvic Mesh Products were more effective than other means of treatment for these conditions for which they were implanted. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiffs, and the public at large.

62. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, Plaintiffs, Plaintiffs' healthcare providers, and the FDA.

63. The information distributed to the public, the medical community, the FDA, and Plaintiffs by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Pelvic Mesh Products.

64. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiffs, regarding the safety of the Pelvic Mesh Products specifically, that the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns, and that the Pelvic Mesh Products were as safe as other means of treating vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

65. Defendants intentionally failed to inform the public, including Plaintiffs, of the high failure rate including erosion, the difficulty of removing the mesh, and the risk of permanent injury.

66. Defendants chose to over-promote the safety, efficacy and benefits of the Pelvic Mesh Products instead.

67. Defendants' intent and purpose in making these misrepresentations was to deceive the public, the medical community, and Plaintiffs; to gain the confidence of the public, the medical community, and Plaintiffs; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Products; and induce Plaintiffs, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Pelvic Mesh Products.

68. Upon information and belief, Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Pelvic Mesh Products did not present serious health risks.

69. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

70. These representations, and others made by Defendants, were made with the intention of deceiving Plaintiffs, Plaintiffs' healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiffs, and Plaintiffs' healthcare professionals, to rely on misrepresentations, and caused Plaintiffs to purchase, rely, use, and

request the Pelvic Mesh Products, and caused her healthcare professionals to dispense, recommend, or prescribe the Pelvic Mesh Products.

71. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of Pelvic Mesh Products known to be dangerous and defective, and/or not as safe as other alternatives. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Pelvic Mesh Products.

72. At the time the representations were made, Plaintiffs and Plaintiffs' healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Pelvic Mesh Products. Plaintiffs did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiffs discover the false representations of Defendants, nor would Plaintiffs with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

73. Had Plaintiffs known the true facts about the dangers and serious health and/or safety risks of the Pelvic Mesh Products, or in the case of the Prolift System, that the Defendants had not sought nor obtained FDA clearance for the product, Plaintiffs would not have purchased, used, or relied on Defendants' Pelvic Mesh Products.

74. At all times relevant herein, the Pelvic Mesh Products were widely advertised and promoted by the Defendants as a safe and effective treatment for vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele. Defendants minimized the risks posed to rectocele and vaginal prolapse patients with implantation of the Pelvic Mesh Products.

75. At all times relevant to this action, Defendants knew that the Pelvic Mesh Products were not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries including, but not limited to, erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theater for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

76. Defendants failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

77. At all relevant times herein, Defendants continued to promote Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

78. In doing so the Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Pelvic Mesh Products for treatment of vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

79. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiffs and the general public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products system

including, but not limited to, mesh erosion, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

80. The Pelvic Mesh Products as designed, manufactured, distributed sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of pelvic health safety.

81. At all times herein mentioned, the employees, agents, officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned Pelvic Mesh Products when they knew of the hazards and dangerous propensities of said Pelvic Mesh Products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiffs.

V. FRAUDULENT CONCEALMENT

82. Defendants' failure to document or follow up on the known defects in its product, and concealment of known defects, constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

83. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed the defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians. Instead of revealing the defects, Defendants continued to represent its Pelvic Mesh Products as safe for their intended use.

84. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their Pelvic Mesh Products.

Because of Defendants' concealment of the true character, quality and nature of their Pelvic Mesh Products, Defendants are estopped from relying on any statute of limitations defense.

85. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiffs, physicians and the public.

86. Defendants' acts before, during and/or after the act causing Plaintiffs' injury prevented Plaintiffs from discovering the injury or cause thereof.

87. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiffs.

88. Defendants' conduct, as described in the preceding paragraphs, also amounts to a continuing tort, and continues up through and including the date of the filing of Plaintiffs' Complaint.

VI. CAUSES OF ACTION

COUNT I: NEGLIGENCE

89. Paragraphs 1-88 of the First Amended Master Complaint are hereby incorporated by reference as if fully set forth herein.

90. Defendants had a duty to individuals, including Plaintiffs, to exercise reasonable and ordinary care in the manufacture, design, labeling, packaging, testing, instruction, warning, selling, marketing, distribution, and training related to its Pelvic Mesh Products.

91. Defendants breached their duty of care and were negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing, and distribution of the Pelvic Mesh Products in one or more of the following respects:

a. Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;

b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;

c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;

d. Failing to use reasonable care in inspecting the Products so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;

e. Failing to use reasonable care in training its employees and health care providers related to the use of the Products so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;

f. Failing to use reasonable care in instructing and/or warning health care providers, the FDA and the public as set forth herein of risks associated with the Products, so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;

g. Failing to use reasonable care in marketing and promoting the Products, so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiffs;

h. In negligently and carelessly promoting the use of the Pelvic Mesh Products to physicians who had not received sufficient training to master the techniques necessary for implantation of the device into the Plaintiffs;

i. Otherwise negligently or carelessly designing, manufacturing, marketing, distributing, warning, labeling studying, testing or selling the Pelvic Mesh Products, and;

j. In the case of the Prolift System, failing to use reasonable care in seeking and obtaining FDA clearance prior to marketing and selling the device for implantation into the human body.

92. Failed to conduct post-market vigilance, or surveillance, by:

a. Monitoring or acting on findings in the scientific and medical literature; and

b. Monitoring or investigating and evaluating reports in the FDA adverse event databases for their potential significance for defendants' Pelvic Mesh Products.

93. Failed to comply with manufacturer requirements of the Medical Device Reporting (MDR) Regulations, specifically:

a. Failed to report MDRs (Medical Device [adverse event] Reports); and

b. Failed to investigate reports of serious adverse events.

94. As a direct and proximate result of Defendants' negligence, Plaintiffs have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages, and/or death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II

STRICT LIABILITY – MANUFACTURING DEFECT

95. Paragraphs 1-94 of the First Amended Master Complaint are hereby incorporated by reference as if fully set forth herein.

96. The Pelvic Mesh Product implanted in Plaintiffs was not reasonably safe for its intended use and was defective with respect to its manufacture, as described herein, in that Defendants deviated materially from their design and manufacturing specifications and/or such

design and manufacture posed an unreasonable risk of harm to Plaintiffs in whom the Pelvic Mesh Products were implanted.

97. The Defendants' Pelvic Mesh Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

98. The Pelvic Mesh Products create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products.

99. Defendants have intentionally and recklessly manufactured, the Pelvic Mesh Products with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interests above the health and safety of the Plaintiffs and others.

100. As a direct and proximate result of the Defendants' defective manufacture of the Pelvic Mesh Products, Plaintiffs have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages, and/or death.

101. The Defendants are strictly liable in tort to the Plaintiffs for their wrongful conduct.

WHEREFORE, Plaintiffs demand judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT III

STRICT LIABILITY – FAILURE TO WARN

102. Paragraphs 1-101 of the First Amended Master Complaint are hereby incorporated by reference as if fully set forth herein.

103. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants' Pelvic Mesh Products.

104. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers as to the risks and benefits of the Defendants' Pelvic Mesh Products, given the Plaintiffs' conditions and need for information.

105. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

106. In addition, the Pelvic Mesh Products were defective due to the lack of necessary and appropriate warnings regarding, but not limited to, the following:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, fragmentation, disintegration and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Products;

f. the risk of chronic infections resulting from the Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. the need for corrective or revision surgery to adjust or remove the Products;

j. the severity of complications that could arise as a result of implantation of the Products;

k. the hazards associated with the Products;

l. the Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

107. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiffs.

108. As a direct and proximate result of the Pelvic Mesh Products' aforementioned defects, Plaintiffs have been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages, and/or death.

109. The Defendants are strictly liable in tort to the Plaintiffs for their wrongful conduct.

WHEREFORE, Plaintiffs demand judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT IV

STRICT LIABILITY – DEFECTIVE PRODUCT

110. Paragraphs 1-109 of the First Amended Master Complaint are hereby incorporated by reference as if fully set forth herein. At the time of Plaintiffs'' injuries, the Defendants' Pelvic Mesh Products were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiffs, and the warnings labels, and instructions were deficient.

111. The Defendants' Pelvic Mesh Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

112. Plaintiffs from Alaska, Arizona, California, District of Columbia, Florida, Hawaii, Illinois, Iowa, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, Minnesota, New Mexico, New York, North Dakota, Oklahoma, Oregon, Rhode Island, Utah, Vermont, Washington, D.C., West Virginia, Wisconsin, Wyoming and such other

states where the common law, the *Restatement of Torts (Second)* and/or the *Restatement of Torts (Third)* are adopted, bring strict product liability claims under the common law, *Section 402A of the Restatement of Torts (Second), and/or Restatement of Torts (Third))* against Defendants.

113. Plaintiffs from jurisdictions that provide a statutory cause of action for strict liability assert each of these claims against Defendants.

114. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V
STRICT LIABILITY – DESIGN DEFECT

115. Plaintiffs incorporate by reference paragraphs 1-114 of this First Amended Master Complaint as if fully set forth herein.

116. The Pelvic Mesh Product implanted in Plaintiffs was not reasonably safe for its intended use and was defective as described herein with respect to its design. As previously stated, the Products' design defects include, but are not limited to:

a. the use of polypropylene material and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the propensity of the Products for particle loss or "shedding", which causes a chronic inflammatory response and fibrotic reaction, and results in continuing injury over time; the lack of porosity of the Products, which leads to fibrotic bridging and results in continuing injury over time; and

i. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

117. As a direct and proximate result of the Product's aforementioned defects as described herein, Plaintiffs experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, other damages, and death.

118. Defendants are strictly liable to Plaintiffs for designing a defective product.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI

COMMON LAW FRAUD

119. Plaintiffs incorporate by reference paragraphs 1-118 of this First Amended Master Complaint as if fully set forth herein.

120. Defendants falsely and fraudulently represented and continue to represent to the medical and healthcare community, Plaintiffs, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective.

121. The representations made by Defendants were, in fact, false. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Pelvic Mesh Products.

122. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiffs, and the public, and also inducing the medical community, Plaintiffs, and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary

incontinence and/or prolapse, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiffs.

123. In representations to Plaintiffs and/or to Plaintiffs' healthcare providers, Defendants fraudulently concealed and intentionally or recklessly omitted the following material information:

a) That the Defendants' Pelvic Mesh Products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b) That the Defendants' Pelvic Mesh Products were more effective than other products and procedures available to treat incontinence and/or prolapse;

c) That the risk of adverse events with the Defendants' Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

d) The Defendants' Pelvic Mesh Products were not adequately tested;

e) That the limited clinical testing revealed the Defendants' Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

f) That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

g) That Defendants deliberately chose to forego studies that might reveal the true rate of adverse events or otherwise necessitate the need to reveal information as to adverse events to the Plaintiff, the medical community, or the regulatory authorities;

h) That Defendants were aware of dangers in the Defendants' Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

i) That the Defendants' Pelvic Mesh Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

j) That patients needed to be monitored more regularly than usual while using the Defendants' Pelvic Mesh Products and that in the event the products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;

k) That the Defendants' Pelvic Mesh Products were manufactured negligently;

l) That the Defendants' Pelvic Mesh Products were manufactured defectively;

m) That the Defendants' Pelvic Mesh Products were designed negligently, and designed defectively; and

n) In the case of the Prolift System, that the Defendants' had not sought nor obtained FDA clearance at the time it began marketing and selling the product.

124. Defendants were under a duty to disclose to Plaintiffs and their physicians, the defective nature of the Defendants' Pelvic Mesh Products, including, but not limited to, the heightened risks of erosion, failure, and permanent injury.

125. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Defendants' Pelvic Mesh Products.

126. Defendants' concealment and omissions of material fact concerning the safety of the Products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause Plaintiffs' physicians and healthcare providers to purchase, prescribe, and/or dispense the Pelvic Mesh Products; and/or to mislead Plaintiffs into reliance and cause Plaintiffs to use the Defendants' Pelvic Mesh Products.

127. At the time these representations were made by Defendants, and at the time Plaintiffs used the Pelvic Mesh Products, Plaintiffs were unaware of the falsehood of these representations, and reasonably believed them to be true.

128. Defendants knew and had reason to know that the Defendants' Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Defendants' Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

129. In reliance upon these false representations, Plaintiffs were induced to, and did use the Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiffs and their physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Defendants' Pelvic Mesh Products, as described in detail herein.

130. Plaintiffs reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the Defendants' Pelvic Mesh Products.

131. Having knowledge based upon Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring Plaintiffs, the public, and Plaintiffs' healthcare providers and physicians, that the Defendants' Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of Defendants' research and testing, or lack

thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiffs, and the public at large.

132. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiffs, Plaintiffs' healthcare providers, and the United States Food and Drug Administration ("FDA").

133. The information distributed to the public, the medical community, the FDA, and Plaintiffs, by Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Defendants' Pelvic Mesh Products.

134. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiffs, regarding the safety of the Defendants' Pelvic Mesh Products specifically that the Products did not have dangerous and/or serious adverse health safety concerns, and that the Defendants' Pelvic Mesh Products were as safe or safer than other means of treating stress urinary incontinence and/or prolapse.

135. Defendants intentionally failed to inform the public, including Plaintiffs, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

136. Defendants chose to over-promote the purported safety, efficacy and benefits of the Defendants' Pelvic Mesh Products instead.

137. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiffs; to gain the confidence of the public, the medical community, and Plaintiffs; to falsely assure them of the quality and fitness for use of the Products; and induce Plaintiffs, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Defendants' Pelvic Mesh Products.

138. Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Defendants' Pelvic Mesh Products had innovative beneficial properties and did not present serious health risks.

139. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

140. These representations, and others made by Defendants, were made with the intention of deceiving and defrauding Plaintiffs, Plaintiffs' healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiffs, and their respective healthcare professionals, to rely on misrepresentations, and caused Plaintiffs to purchase, rely, use, and request the Defendants' Pelvic Mesh Products and their healthcare professionals to dispense, recommend, or prescribe the Defendants' Pelvic Mesh Products.

141. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Defendants' Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

142. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiffs, as well as their healthcare professionals, into a false sense of security, so that Plaintiffs and their healthcare providers would rely on Defendants' representations, and Plaintiffs would request and purchase the Defendants' Pelvic Mesh Products, and that their healthcare providers would dispense, prescribe, and recommend the Defendants' Pelvic Mesh Products.

143. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Defendants' Pelvic Mesh Products.

144. At the time the representations were made, Plaintiffs and their healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Defendants' Pelvic Mesh Products. Plaintiffs did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiffs discover the false representations of Defendants, nor would Plaintiffs with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

145. Had Plaintiffs known the true facts about the dangers and serious health and/or safety risks of the Defendants' Pelvic Mesh Products, Plaintiffs would not have purchased, used, or relied on Defendants' Pelvic Mesh Products.

146. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiffs.

147. As a direct and proximate result of Defendants' conduct, Plaintiffs experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and

procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, other damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII

FRAUDULENT CONCEALMENT

148. Plaintiffs incorporate by reference paragraphs 1-147 of this First Amended Master Complaint as if fully set forth herein.

149. Plaintiffs from Alabama, Arizona, California, Colorado, Delaware, Georgia, Illinois, Iowa, Kansas, Maine, Maryland, Michigan, Mississippi, Missouri, Nebraska, New York, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin and any other states that recognize such a cause of action bring this fraudulent concealment claim under the common law.

150. Throughout the relevant time period, Defendants knew that their Pelvic Mesh Products were defective and unreasonably unsafe for their intended purpose.

151. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiffs, their physicians and the medical community that their Pelvic Mesh Products were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

152. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products because:

a) Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants' Pelvic Mesh Products;

b) Defendants knowingly made false claims about the safety and quality of the Defendants' Pelvic Mesh Products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c) Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' Pelvic Mesh Products from Plaintiffs.

153. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Pelvic Mesh Products.

154. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiffs would request and purchase the Defendants' Pelvic Mesh Products, and that her healthcare providers would dispense, prescribe, and recommend the Defendants' Pelvic Mesh Products, and Plaintiffs justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendants' Pelvic Mesh Products.

155. Defendants, by concealment or other action, intentionally prevented Plaintiffs and Plaintiffs' physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of the Defendants' Pelvic Mesh Products, and are subject to the same liability to Plaintiffs for Plaintiffs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Defendants' Pelvic Mesh Products' lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiffs were thus prevented from discovering the truth. Defendants therefore have liability for

fraudulent concealment under all applicable law, including, *inter alia*, *Restatement (Second) of Torts* § 550 (1977).

156. As a proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII

CONSTRUCTIVE FRAUD

157. Plaintiffs incorporate by reference paragraphs 1-156 of this First Amended Master Complaint as if fully set forth herein.

158. Defendants are in a unique position of knowledge concerning the quality, safety and efficacy of the Defendants' Pelvic Mesh Products, which knowledge is not possessed by Plaintiffs or their physicians, and Defendants thereby hold a position of superiority over Plaintiffs and their physicians.

159. Despite their unique and superior knowledge regarding the defective nature of the Defendants' Pelvic Mesh Products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Defendants' Pelvic Mesh Products, as compared to other products and forms of treatment.

160. For example, scientists in the recent study published in *Obstetrics & Gynecology*, August, 2010, found that the complication rate was so high that the clinical trial was halted early.

161. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the Defendants' Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Products.

162. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the Defendants' Pelvic Mesh Products. Plaintiffs and the medical community have relied upon Defendants' representations.

163. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their medical providers and engaged in constructive fraud in their relationship with Plaintiffs and their medical providers. Plaintiffs reasonably relied on Defendants' representations.

164. As a proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX

NEGLIGENT MISREPRESENTATION

165. Plaintiffs incorporate by reference paragraphs 1-164 of this First Amended Master Complaint as if fully set forth herein. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs, and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

166. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

167. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiffs, Plaintiffs' physicians, and the medical and healthcare community.

168. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know,

that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

169. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

170. Plaintiffs incorporate by reference paragraphs 1-169 of this First Amended Master Complaint as if fully set forth herein.

171. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Pelvic Mesh Products to Plaintiffs, carelessly and negligently concealing the harmful effects of the Defendants' Pelvic Mesh Products from Plaintiffs, and carelessly and negligently misrepresented the quality, safety and efficacy of the products.

172. Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that Plaintiffs have sustained and will continue to sustain emotional distress,

severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase the Pelvic Mesh Products sold and distributed by Defendants.

173. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XI

BREACH OF EXPRESS WARRANTY

174. Plaintiffs incorporate by reference paragraphs 1-173 of this First Amended Master Complaint as if fully set forth herein.

175. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Products.

176. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Products be used in the manner that Plaintiffs in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that each product was of merchantable quality, that their side effects were minimal and comparable to other pelvic mesh products, and that they were adequately tested and fit for their intended use.

177. At all relevant times, Defendants were aware that consumers, including Plaintiffs, would use the Pelvic Mesh Products; which is to say that Plaintiffs were foreseeable users of the Defendants' Pelvic Mesh Products.

178. Plaintiffs and/ or their implanting physicians were at all relevant times in privity with Defendants.

179. The Defendants' Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiffs and their implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

180. Defendants breached various express warranties with respect to the Pelvic Mesh Products including the following particulars:

a) Defendants represented to Plaintiffs and their physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

b) Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Pelvic Mesh Products were as safe, and/or safer than other alternative procedures and devices, that complications are rare, and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market and that complications were not, in fact, rare; and

c) Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the products.

181. In reliance upon Defendants' express warranties, Plaintiffs were implanted with the Defendants' Pelvic Mesh Products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

182. At the time of making such express warranties, Defendants knew or should have known that the Defendants' Pelvic Mesh Products do not conform to these express representations because the Defendants' Pelvic Mesh Products were not safe and had numerous

serious side effects, many of which are common and Defendants did not accurately warn about, thus making the Defendants' Pelvic Mesh Products unreasonably unsafe for their intended purpose.

183. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the Public relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Defendants' Pelvic Mesh Products.

184. Defendants breached their express warranties to Plaintiffs in that the Defendants' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

185. Defendants' breaches constitute violations of common law principles and the statutory provisions of the Plaintiffs' respective states.

186. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII

BREACH OF IMPLIED WARRANTY

187. Plaintiffs incorporate by reference paragraphs 1-186 of this First Amended Master Complaint as if fully set forth herein.

188. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Products.

189. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Products be implanted for the purposes and in the manner those Plaintiffs or Plaintiffs' implanting physicians in fact used they and Defendants impliedly warranted each product to be of merchantable quality, safe and fit for such use, even though they were not adequately tested.

190. Defendants were aware that consumers, including Plaintiffs or Plaintiffs' physicians, would implant the Defendants' Pelvic Mesh Products in the manner directed by the instructions for use; which is to say that Plaintiffs or Plaintiffs' Decedents were foreseeable users of the Defendants' Pelvic Mesh Products.

191. Plaintiffs and/or their physicians were at all relevant times in privity with Defendants.

192. The Defendants' Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiffs or Plaintiffs' physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

193. Defendants breached various implied warranties with respect to the Defendants' Pelvic Mesh Products, including, but not limited to, the following particulars:

a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;

b) Defendants represented that the Defendants' Pelvic Mesh Products were safe, and/or safer than other alternative devices or procedures and that complications were rare, and fraudulently concealed information, which demonstrated that the Defendants' Pelvic Mesh Products were not as safe or safer than alternatives available on the market; and

c) Defendants represented that the Defendants' Pelvic Mesh Products were more efficacious than alternative pelvic mesh products and procedures and fraudulently concealed information, regarding the true efficacy of the Defendants' Pelvic Mesh Products.

194. In reliance upon Defendants' implied warranty, Plaintiffs used the Pelvic Mesh Products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

195. Defendants breached their implied warranty to Plaintiffs in that the Defendants' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of Common Law principles and the statutory provisions of the Plaintiffs' respective states.

196. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIII

VIOLATION OF CONSUMER PROTECTION LAWS

197. Plaintiffs incorporate by reference paragraphs 1-196 of this First Amended Master Complaint as if fully set forth herein.

198. Plaintiffs purchased and used the Defendants' Pelvic Mesh Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

199. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for the Defendants' Pelvic Mesh Products, and would not have incurred related medical costs and injury.

200. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Pelvic Mesh Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

201. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b) Advertising goods or services with the intent not to sell them as advertised; and,

c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

202. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Pelvic Mesh Products. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Products.

203. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Products.

204. Had Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the Products, and would not have incurred related medical costs.

205. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed below.

206. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

207. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the statutory provisions of the Plaintiffs' respective states.

208. Under the applicable statutes to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

209. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh Products were fit to be used for the purpose for which they were intended, when in fact they

were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

210. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

211. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Products and failed to take any action to cure such defective and dangerous conditions.

212. Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

213. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

214. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

215. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses, injuries and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XIV

GROSS NEGLIGENCE

216. Plaintiffs incorporate by reference paragraphs 1-215 of this First Amended Master Complaint as if fully set forth herein.

217. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

218. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

219. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

220. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XV

UNJUST ENRICHMENT

221. Plaintiffs incorporate by reference paragraphs 1-220 of this First Amended Master Complaint as if fully set forth herein. Defendants are and at all times relevant were the manufacturers, sellers, and/or suppliers of the Defendants' Pelvic Mesh Products.

222. Plaintiffs paid for the Defendants' Pelvic Mesh Products for the purpose of treatment of stress urinary incontinence and/ or pelvic organ prolapse or other similar conditions.

223. Defendants have accepted payment by Plaintiffs and others on Plaintiffs' behalf for the purchase of the Defendants' Pelvic Mesh Products.

224. Plaintiffs have not received the safe and effective medical devices for which they paid.

225. It would be inequitable for Defendants to keep this money since Plaintiffs did not in fact receive a safe and effective medical device as represented by Defendants

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVI

LOSS OF CONSORTIUM

226. Plaintiffs incorporate by reference paragraphs 1-225 of this First Amended Master Complaint as if fully set forth herein.

227. At all relevant times hereto, Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of the Pelvic Mesh Products and Plaintiffs' injuries.

228. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

229. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

230. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

231. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

232. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs, and/or intimate partners of the aforesaid women, have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners are entitled by law.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVII

PUNITIVE DAMAGES

233. Plaintiffs incorporate by reference paragraphs 1-232 of this First Amended Master Complaint as if fully set forth herein.

234. Defendants sold their Products to Plaintiffs' healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

235. Defendants sold the Products to Plaintiffs' health care providers and other health care providers throughout the United States in spite of their knowledge that their Products

can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this First Amended Master Complaint, thereby causing severe and debilitating injuries suffered by the Plaintiffs.

236. At all times relevant hereto, Defendants knew or should have known that the Defendants' Pelvic Mesh Products were inherently dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

237. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Defendants' Pelvic Mesh Products.

238. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety and efficacy of the Defendants' Pelvic Mesh Products.

239. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the Defendants' Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods products and/or procedures and/or treatment.

240. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the Defendants' Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise healthcare providers, the public and the FDA of same.

241. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by the Defendants' Pelvic Mesh Products.

242. Notwithstanding the foregoing, Defendants continue to aggressively market the Defendants' Pelvic Mesh Products to consumers, without disclosing the true risk of side effects and complications.

243. Defendants knew of the Defendants' Pelvic Mesh Products defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Defendants' Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiffs, in conscious and/or reckless disregard of the foreseeable harm caused by the Defendants' Pelvic Mesh Products.

244. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiffs, the serious side effects of the Defendants' Pelvic Mesh Products in order to ensure continued and increased sales.

245. Defendants' intentionally, reckless and/or grossly negligent failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using the Defendants' Pelvic Mesh Products against their benefits.

246. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs have required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical care and/or hospital care and medical services.

247. Defendants have engaged in conduct entitling Plaintiffs to an award of punitive damages pursuant Common Law principles and the statutory provisions of the Plaintiffs' respective states.

248. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, punitive damages, and such further relief as the Court deems equitable and just.

COUNT XVIII: DISCOVERY RULE AND TOLLING

249. Plaintiffs incorporate by reference paragraphs 1-248 of this First Amended Master Complaint as if fully set forth herein.

250. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

251. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

252. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and

damages, and their relationship to the Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

253. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant(s) are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the true risks associated with the Products. As a result of Defendants' fraudulent concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
2. Restitution and disgorgement of profits;
3. Reasonable attorneys' fees;
4. The costs of these proceedings;
5. All ascertainable economic damages;

6. Punitive damages;

7. Survival damages (if applicable);

8. Wrongful death damages (if applicable); and

9. Such other and further relief as this Court deems just and proper.

Dated: August 31, 2012

Respectfully submitted,

/s/ D. Renee Baggett

D. RENEE BAGGETT

Aylstock, Witkin, Kreis and Overholtz, PLC
17 E. Main Street, Suite 200
Pensacola, FL 32563
850-202-1010
850-916-7449
Rbaggett@awkolaw.com

/s/ Thomas P. Cartmell

THOMAS P. CARTMELL

Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
http://www.wagstaffcartmell.com/

Plaintiffs' Co-Lead Counsel

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all issues.

Respectfully submitted,

Dated: August 31, 2012

/s/ D. Renee Baggett

D. RENEE BAGGETT

Aylstock, Witkin, Kreis and Overholtz, PLC
17 E. Main Street, Suite 200
Pensacola, FL 32563
850-202-1010
850-916-7449
Rbaggett@awkolaw.com

/s/ Thomas P. Cartmell

THOMAS P. CARTMELL

Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com

Plaintiffs' Co-Lead Counsel